Received
9/15/2000
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COVANCE
THE DEVELOPMENT SERVICES COMPANY

FAX
Covance Clinical Research Unit Inc.
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Madison, Wisconsin 53703
Tel: 608/283-6060
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- SICA need proposal
- what do you do with subjects in Main study who get "SICK"

Date: 31 August 2000

From: Brigitte M. Kochan

To: Robert G. Elves Fax Number: 804-274-2891

Philip Morris, USA

Re: Pilot Total Exposure Study - Proposal

Pages (including cover): 48

Dear Dr. Elves:

Attached is our proposal for the Pilot Total Exposure Study. We have made every effort to provide as clear a picture as possible of our capabilities and our approach to managing and conducting the various aspects of this project. We look forward to discussing these with you in the near future.

Included is a preliminary timeline for protocol and CRF development, IRB submission, and recruiting and screening. This timeline may be adjusted depending on the time it takes to complete each review cycle. With the current timeline, we anticipate enrollment to start around the first of the year 2001. I will continue to work on this timeline to give you a better estimate of report delivery timelines.

One additional factor to consider is that the lead times for the synthesis of standard materials required for the validation of some of the assays can typically be up to 2 months. Therefore the urgency to get approval for the analytical method development is of paramount importance.

A Letter of Intent is being developed to initiate method development work while the contract is being negotiated. This will be forwarded to Phillip Morris, USA under separate cover.

We appreciate the opportunity to provide a bid for this project and look forward to future discussions.

Regards,

Brigitte

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